

interview of June 7, 2004. Minor errors in the resultant claims are corrected by the present amendments. The Supplemental Notice of Allowability includes an Examiner's Amendment that correctly reflects the substance of a telephone interview on August 16, 2004.

Comments on Reasons for Allowance

The Notice of Allowability includes a statement by the Examiner of his reasons for allowance. The Examiner indicates that,

The specification is enabled only for amantadine as non-spermine/non-spermidine substrate for SSAT, because the specification explicitly demonstrates that only acetylamantadine was detected with amantadine as a substrate for SSAT and that transgenic mice over expressing SSAT had a level of SSAT activity in the liver that is 4 fold higher with amantadine as substrate than that observed in non-transgenic mouse (See Specification, Page 12, Lines 4-6). Furthermore, mouse liver preparation as SSAT source did not show spermidine acetylation (See Specification, Page 11, Line 17).

Applicants do not agree that the specification enables only the use of amantadine as a non-spermine/non-spermidine substrate for SSAT. The Examiner has not made a *prima facie* case of lack of enablement. Enablement is a question of whether or not undue experimentation is required to practice the invention throughout the full scope of the claims. The question of undue experimentation is evaluated by weighing eight different factors, as explained for example in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). The mere allegation that the specification only discloses amantadine as a substrate for

SSAT<sup>1</sup> according to the invention is not sufficient to establish lack of enablement.

Furthermore, the specification provides assays useful to determine if any particular compound is useful as a non-spermine/non-speridine substrate for SSAT. The reader is referred to the inhibition assays, the *in vitro* assays and the *in vivo* assay described at pages 6-11 of the specification. The specification also provides guidance that non-diaminopropane substituted compounds are useful in the invention (e.g. original claim 12) and the use of amantadine as a substrate in working examples urges one to use an adamantane derivative as a starting point for experimentation.

Despite Applicants' disagreement with the Examiner on the question of the scope of enablement, Applicants have accepted the Examiner's Amendment to advance prosecution of the application. Applicant reserves the right to pursue the broader claims in an application filed pursuant to 35 USC § 120.

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<sup>1</sup> The allegation is not entirely correct. While amantadine is the only working example described, the specification further discloses at least that a non-diaminopropane SSAT substrate can be used.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By Mark J. Nuell  
Mark J. Nuell, #36,623

DRN/mua  
0030-0206P

P.O. Box 747  
Falls Church, VA 22040-0747  
(703) 205-8000

Attachment(s)